

Plasma Protein Therapies
*Reimbursement: Access, Choice and
Innovation*

**HHS Advisory Committee on Blood Safety
& Availability**

August 26, 2004 Washington, DC

- Health Policy
- Overview of Industry Challenges
- Medicare
- Medicaid
- Conclusions

- Assure choice and access to plasma derived and recombinant analog therapies
- Assure adequate and appropriate reimbursement
Reimbursement=Access
- Expand partnerships with key stakeholders
- Create greater community and political awareness

- Ensure choice and access to critical life-saving therapies for a broad cohort of patients with congenital diseases and chronic conditions across all sites of service:
 - Inpatient
 - Outpatient
 - Physician Office
 - Homecare

- Consolidating industry
- Declining product revenues
 - Reduced reimbursement for plasma therapies and government mandated price reductions will challenge manufacturers to further reduce costs and investment
 - The challenge for the plasma therapeutics industry is to continue to meet consumer demand and fund product development given increasing regulatory and economic constraints

- Plasma Therapeutics are for small patient populations unlike the mass markets for traditional pharmaceuticals
- Complex and lengthy manufacturing process
- Cost of starting materials
- Investment in working capital, plant and equipment to manufacture plasma therapeutics is ongoing
- Applicability of generic biologics
 1. Stymies innovation and slows response to consumer demands

Policy makers must differentiate plasma derived and recombinant analogs from traditional pharmaceuticals

- Blood Clotting Factors (BCF)
- Intravenous Immune Globulin (IVIG)
- Alpha 1 Proteinase Inhibitor (A1PI)

Key Message: MMA has put into place new reimbursement methodologies for various sites of service - - impact on access to care for Medicare beneficiaries unknown

Inpatient

- Reimbursement structure based on DRGs
- Add-on payment since 1990

Hospital Outpatient

- MMA - - sole source classification (88% of AWP in 04, 83% AWP in 05)

Physician Office & Homecare

- MMA - - ASP+6 in 05), plus a \$.05 add-on
- 80% provider/20% consumer copay
- proposed rule (29% reduction R FVIII)
 - comments due 9/24
- 2006 competitive bidding or ASP+6

Inpatient

- Reimbursement structure based on DRGs
- Services bundled (no separate payment)

Hospital Outpatient

- MMA - - sole source classification (88% of AWP in 04, 83% AWP in 05)

Physician Office

- MMA - - ASP+6 in 05
- 80% provider/20% consumer copay
- 2006 exempt from competitive bidding

Homecare

- MMA - - PID only, coverage for the drug only

Inpatient

- Reimbursement structure based on DRGs

Hospital Outpatient

- 05 proposed rule, single indication orphan drug indication
- the higher of 88% of AWP or 106% of ASP, payment
- capped at 95% of AWP

Physician Office

- ASP +6 in 05
- 80% provider/20% consumer copay
- 2006 ASP+6 or competitive bidding

Homecare

- **GAP:** No coverage in home setting
- Goal for 109th Congress

- HOPPS proposed rule
 - 29% reduction
 - Of the designated orphans, A1PI is one of only two therapies to decrease
- Two new entrants to market
 - Invested millions of dollars per patient
 - Reimbursement drastically cut

Question: Where is the recognition for innovation?

State Budget Crisis

- Economic Downturn
- Revenue Growth Plunges
- Medicaid Drug Budgets Increasing at Double Digit Growth Rate
- Driving Debate

- States Still Looking for a Quick Fix
 - Prior Authorization
 - Preferred Drug Lists
 - Limits on Brand Name Drugs
 - Shift to Managed Care (PBMs)
 - Price Controls

- Federal and State reimbursement policies impact access, choice and innovation
 - Sole Source Provider Contracts result in limitations on access and choice
 - Competitive Bidding is an unproven private market methodology that will impact access to care and result in restrictions on choice (IVIg exception)
 - Trend - - - reimbursement steadily declines across sites of service (prospective payment & MMA)

- Outreach to consumer and provider organizations, education of policy makers about the unique nature of the plasma therapeutics industry
- Must work together on reimbursement issues to ensure access and choice of therapies in the future
- Reimbursement drives:
 - Access
 - Choice
 - Innovation